TOBACCO HAS DISTRACTED THE FDA FROM ITS DUTIES

No one -- including the tobacco companies -- disagrees when it comes to the issue of teenage smoking. Simply put, the decision to smoke is a decision to be made by adults, not by teenagers.

But putting the Food and Drug Administration in charge of youth smoking, as proposed by the Clinton Administration, would be a serious mistake.

There is widespread, bipartisan agreement that the FDA has been neglecting its vital missions, such as timely approval of new drugs and medical devices, and inspecting food processing plants here and abroad. Congressional hearings last year focused on the need for FDA reform.

Not only is the FDA endangering lives by failing to timely approve new products, evidence is mounting that medical device manufacturers and biotechnology companies are moving their operations overseas to avoid overly-burdensome FDA regulation. That means that good jobs are being exported.

FDA Commissioner David Kessler needs to put his house in order, and focus his efforts on speeding the review process for breakthrough drugs and technology that can save lives.

Instead, he is obsessed with expanding FDA's jurisdiction to tobacco products -- in clear defiance of 50 years of legal precedent.

Commissioner Kessler defends his focus on tobacco as necessary to protect children. But the FDA is not empowered to address every public health problem. Congress has considered this problem and decided that State enforcement of minimum age laws, not FDA regulation, is the best way to keep children away from cigarettes.

In 1992, Congress passed amendments to the Public Health Service Act which placed responsibility for solving the youth smoking issue where it belongs -- in the 50 States where the sale of tobacco to minors is already illegal. It took the Department of Health and Human Services over three years to promulgate the rules necessary for States to comply with this important legislation. Apparently, the Administration became so entranced with its unauthorized tobacco program, that it forgot that Congress had directed it to implement this legislatively-mandated solution to youth smoking.

The Administration's effort to bypass Congress -- and impose new law by executive fiat -- threatens our Constitution, which places the responsibility for enacting new laws with Congress.

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Congress has repeatedly reserved to itself policy making powers regarding tobacco. Congress has specifically chosen to exclude the FDA from the regulation of tobacco, a matter which affects not only public health issues, but the personal choices of millions of American adults. Over the past 90 years, Congress has considered whether to grant authority over tobacco to the FDA several times. Each time, it has refused to do so.

Previous FDA commissioners and the courts consistently have upheld this congressional intent to deny the FDA authority over tobacco. The reason is simple: the FDA's job is to approve products that are safe and effective for an intended use. FDA, however, has already concluded that tobacco products do not fit into this category.

In 1994, Commissioner Kessler asked Congress to provide FDA with a "clear direction" on how he should proceed with regard to tobacco. Without waiting for Congress, he then pushed ahead with plans to regulate tobacco, embroiling his agency in public controversy and costly litigation.

The Administration and Commissioner Kessler have proven that they are more interested in grabbing headlines and playing politics than in crafting sensible public policy to combat youth smoking.

Everyone is concerned that kids are smoking. But if the Administration is serious about combating this problem, instead of wasting federal dollars creating new programs, it would continue to focus on helping States enforce the minimum age laws already on their books and leave the FDA to its important public mission -- a mission that doesn't include regulation of tobacco.

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